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■

MEDICAL ASSISTANCE PROGRAM

Proposed Reimbursment of Drug Cost

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

Social and Rehabilitation Service

[45 CFR Part 250]

REIMBURSEMENT OF DRUG COST—MEDICAL ASSISTANCE PROGRAM

Notice of Proposed Rule Making

Notice is hereby given that the regulations set forth in tentative form below are proposed by the Administrator, Social and Rehabilitation Service, with the approval of the Secretary of Health, Education, and Welfare. The proposed regulations implement the provisions of section 1903(i) of the Social Security Act mandating upper limits of reimbursement for prescribed drugs in the medical assistance program administered under title XIX, Social Security Act. The proposed changes are as follows:

Reimbursement Policy for All Prescribed Drugs. Section 1902(a)(30) of the Social Security Act, enacted as part of the 1967 Social Security Amendments, requires that a State medical assistance plan include methods and procedures to safeguard against payments in excess of reasonable charges for drugs, consistent with efficiency, economy, and quality of care. Section 224 of the 1972 Social Security Act Amendments, Pub. L. 92-603, limits Federal financial participation for items or services that do not generally vary significantly in quality from one supplier to another, to the lowest charge levels at which they are widely and consistently available in a locality, except as otherwise specified by the Secretary. The new regulations provide upper limits for reimbursement of the cost of prescribed drugs which are consistent with the 1972 statutory requirement.

Achieving the mandated economies in drug cost reimbursement involves two principal elements: the cost of the drug to the provider and the provider's charge for dispensing. Current regulations under section 1902(a)(30), in effect since 1969, governing the upper limits of reimbursement for prescribed drugs, provide that the State may reimburse providers either on the basis of drug cost plus a fixed dispensing fee, or the usual charge to the general public.

Dispensing Charges. Since 1969, there has been a steady movement toward reimbursement on the basis of cost plus dispensing fee. Of the 49 States and jurisdictions which include prescribed drugs in their Medicaid programs, more than two-thirds now reimburse on this basis. It is also used by a growing number of non-governmental third party programs and an increasing number of retail pharmacists in determining drug charges to the general public. Compared to reimbursement on the basis of "usual charge," the fee system offers several important advantages: it recognizes that the cost of dispensing is not necessarily related to the cost of the drug; it facilitates automated claims processing and speeds the payment of claims; and it lessens the need of monitoring to assure that drug charges to the program do not exceed those to the public.

For these reasons the proposed regulation requires that the method of reimbursement under Medicaid be on the basis of drug cost plus dispensing fee.

Acquisition Costs. In referring to drug cost, current regulations specify "cost as determined by the State." Most States use average wholesale price, Red Book data, Blue Book data, survey results or similar standard costs. Such standard prices are frequently in excess of actual acquisition costs to the retail pharmacist. Thus, to achieve maximum savings to the Medicaid program, the proposal requires the use of actual acquisition cost.

Reimbursement for Unit Dose Dispensing. The proposed regulation also clarifies the use of a dispensing fee for drugs furnished recipients of medical assistance in long term care facilities by pharmacies employing a unit dose system. This system involves the dispensing of only that amount of drug intended to be consumed in a given time period. This method is considered by many to result in both cost savings and increased quality of care. Dollar savings result from paying only for drugs which are actually consumed. Savings also result from reduced personnel costs in long term care facilities but these may be offset to some extent by the relative increase in the dispensing cost paid to the pharmacy. Factors which contribute to increased quality include fewer medical errors, close monitoring of drug intake, and fewer drug interactions.

Cost Limits on Multiple Source Drugs. On November 15, 1974, the Secretary published a proposal for a Pharmaceutical Reimbursement Board which will publish and periodically revise maximum allowable cost (MAC) limitations on the reimbursement of multiple-source drug costs in Departmentally-supported health programs. Under the regulations proposed herein, cost will be limited to the lower of the MAC or actual acquisition cost plus 25 percent of the differential between actual acquisition cost and the established MAC, unless the prescribing physician certifies that a specific brand of a multiple-source drug is medically indicated.

Medicaid recipients also are furnished drugs while they are inpatients in hospitals. Payment for inpatient hospital care under Medicaid is on a reasonable cost basis using the Medicare formula. Since regulations are concurrently being published by the Social Security Administration for Medicare (title XVIII) placing restrictions on the level of reimbursement for multiple source drugs used in hospitals, such restrictions will automatically apply to the State Medicaid programs.

Prior to the adoption of the proposed regulations, consideration will be given to any [illegible] which are received in writing by the [illegible], P.O. Box 2366, Washington, D.C. 20013 [illegible] January 27, 1975. Comments received will be available for public inspection in Room 5328 of the Department's offices at 301 C Street, SW., Washington, D.C. on Monday through Friday of each week from 8:30 a.m. to 5:00 p.m. (Area Code 202-245-0950).

(Sec. 1102, 49 Stat. 647 (42 U.S.C. 1302)) (Catalog of Federal Domestic Assistance Program No. 13.714, Medical Assistance Program)

Dated: October 30, 1974.

JAMES S. DWIGHT, Jr.,
Administrator, Social and Rehabilitation Service.

Approved: November 21, 1974.

CASPAR W. WEINBERGER,
Secretary.

Section 250.30(b)(2) of Part 250, Chapter II, Title 45, Code of Federal Regulations, is revised as set forth below:

§ 250.30 Reasonable charges.

(b) *Upper limits.* * * *

(2) *Drugs.* The upper limit for payment for prescribed drugs—whether legend items (for which a prescription is required under Federal law) or non-legend items—shall be based on the cost of the drug (as determined in accordance with paragraph (b)(2)(ii) of this section) plus a dispensing fee established by the State.

(i) The dispensing fee should be ascertained by analysis of pharmacy operational data which includes such components as overhead, professional services, and profit. Indices to be considered shall include payment practices of other third-party organizations, including other Federal programs.

(a) The dispensing fee may vary according to the size and location of the pharmacy and according to whether the dispensing is done by a physician or by an [illegible] department of an institution and according to whether the drug is a legend or a non-legend item.

(b) The dispensing fee may also vary for prescribed drugs furnished to title XIX recipients in an institutional setting by a pharmacy employing a unit dose system. In such instances the dispensing fee may be either: (*1*) An amount added to the cost of each unit dose furnished by the pharmacy or (*2*) a daily or monthly [illegible] rate per recipient for whom prescribed drugs are being furnished. In either case, the dispensing fee is added to the ingredient cost of the [illegible] drug which is actually [illegible].

(c) In evaluating a dispensing fee by analysis of operational data, the objective of the State agency should be to [illegible] prescription price [illegible] by the general public.

(ii) For each multiple source drug designated by the Pharmaceutical Reimbursement Board [illegible]

cost exceeds the acquisition cost; except that such limitation shall not apply in any case where a physician certifies in writing that only a specific brand of drug can be tolerated by or is effective for a particular patient. For all other prescribed drugs, cost shall be determined on the basis of actual acquisition cost. For the purposes of this section, "actual acquisition cost" means the cost of the product to the provider less any quantity, trade, and promotional discounts and allowances except cash discounts not in excess of 2 percent of cost. It may include warehousing and other distributional costs incurred by a provider who maintains a warehouse separate from his retail place of business. In no case shall the claimed acquisition cost be greater than the lowest cost which would have been incurred if the product had been obtained through a wholesaler.

(iii) The upper limits governing reimbursement by State agencies to providers of prescribed drugs specified in this section shall also apply in cases where prescribed drugs are furnished as part of skilled nursing facility or intermediate care facility services or under prepaid capitation arrangements. Contracts between the State agency and the underwriter, carrier, intermediary, health maintenance organization, or other insurer containing the terms of such prepaid capitation arrangements shall include a provision imposing the same upper limits for reimbursement of prescribed drugs as are imposed by paragraph (b)(2) of this section on the State agency.

[FR Doc.76-37718 Filed 11-26-76;8:45 am]